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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/611,414	06/30/2003	David P. Holden	ABIOS.021A	1954

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APPLIED BIOSYSTEMS  
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FOSTER CITY, CA 94404

EXAMINER
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SIMS, JASON M

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 09/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/611,414

Applicant(s)

HOLDEN ET AL.

Examiner

Jason M. Sims

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-83 is/are pending in the application.
- 4a) Of the above claim(s) 22-83 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 6/13/2005, 8/29/06.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

Applicant's election without traverse of inventive group I, claims 1-21, in the reply filed on 6/30/06 is acknowledged.

Claims 22-83 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventive group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 6/30/06.

Claims 1-21 are the instant claims hereby under examination.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 contains the wording "each cluster associated with a discrete allelic combination," which is vague and indefinite as to what it refers. For example, the claim cites that an intensity component is associated with an allele, but now the intensity information, which forms the data clusters, is associated with an allelic combination. Are the intensity differences not enough to form different clusters? If they are distinct enough to form distinct data clusters, then how does a data cluster, comprising of a particular intensity component that is associated with a particular allele, become associated with a discrete allelic combination? Clearer claim wording is required.

Claim 1 contains the wording "applying the likelihood model to each of the plurality of samples to determine its associated allelic composition," which is vague and indefinite. The word "its" takes on singular meaning referring to the plural phrase "each of the plurality of samples." Clearer claim wording is required.

Claim 1 contains the preamble wording "a method for allelic classification," but the method steps result in determining an "allelic composition." It is unclear as to the metes and bounds of the preamble as the stated "method for allelic classification" does not result in such a classification but rather a determined allelic composition.

Claim 5 contains the wording "wherein the data clusters comprise at least three discrete clusters," which is vague and indefinite. Does each "data cluster" comprise of at least three discrete clusters, which is referred to here as a "data cluster" or are the "data clusters" three discrete clusters themselves? In other words, does the phrase "three discrete clusters" refer to one "data cluster" or three "data clusters?" Clearer claim wording is required.

Claims 6 and 7 contain the same dependent "data clusters," which is vague and indefinite. Are the same "data clusters" associated with a heterozygous and a second homozygous allelic classification? Clearer claim wording is required.

Claim 13 contains the wording "no template control" probe. It is unclear as to what exactly this type of probe refers. Clearer claim wording is required.

Claims 2-4, 8-12, and 14-21 are rejected as being dependent from a rejected claim.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-21 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Under the Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility (published in the O.G. notice (1300 OG 142) on 11/22/2005) a method that does not result in a physical transformation of matter MAY be statutory where it recites a concrete, tangible and useful result; i.e. a practical application.

In the instant case, the claims are directed to a method for allelic classification. In the instant case, the method of claims 1-21 does not result in a physical transformation of matter, nor is any concrete, tangible and useful result produced/recited. Therefore, these claims are not statutory.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical

Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 5-9, 10-11, 16, and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Landers et al (US P/N 6,703,228).

Landers et al. teaches claim 1 at the abstract, col. 25, lines 20-67, col. 3, lines 5-54, col. 6, lines 5-55, col. 26, lines 1-40, col. 30, lines 51-67, col. 31, and col. 32, lines 1-26. The abstract discloses that this invention is a method of genotyping and genomic classification, which represents a method for allelic classification. Landers et al., at cols. 25 and 26, discusses acquiring intensity data from using microarrays from 1,000-10,000s of samples, some of which use several different dyes, which represents acquiring intensity information for a plurality of samples wherein a first intensity is associated with a first allele and a second intensity is associated with a second allele. Landers et al., at col. 3, lines 5-67, discusses using microarray chips containing thousands of samples and using hybridization reactions to acquire intensity information and determine the presence or absence of a particular SNP. It is known to one of ordinary skill in the art that these hybridization reactions for SNP determination involve comparing signal intensities where a particular intensity is associated with a particular allele, which represents a first allele being associated with a first intensity and a second intensity being associated with a second allele. Additionally, Landers et al., at col. 3, discusses determining allele frequencies of an SNP in a population, which represents

identifying one or more data clusters that are associated with a discrete allelic combination and are determined, in part, by comparing the first intensity component relative to the second intensity component. Furthermore, Landers et al., at col. 6 discusses generating genomic patterns for individual genomes based on SNP analysis and frequency and hybridization patterns, which enable a classification of the genome to occur, which represents evaluating intensity information to identify data clusters and each cluster being associated with a particular allele. Landers et al., at col. 31 and 32, discusses using a likelihood model to predict the probability that a sample will have a particular disease classification or that particular data will be linked, which represents generating a likelihood model that predicts probability that a sample resides within a particular cluster and determines a sample and its associated allelic composition.

Landers et al. teaches claims 5-9 at col. 6, lines 4-58, col. 21, lines 7-22, and col. 23, lines 17-41. Landers et al., at col. 21, teaches a definition for a polymorphic region and discusses three possible genotypes for a diploid organism and how studying SNPs is a good way for genotyping these type of complicated genotypes. Landers et al., at col. 6, discusses generating patterns for SNP alleles in different genomes for genomic classification. In addition, Landers et al., at col. 23, discusses using genotyping to determine phenotypes where homozygous or heterozygous genotypes can contribute to phenotypes, which represents that Landers et al. does genotype different genomes that include homozygous and heterozygous genotypes.

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Landers et al. teaches claims 10-11 and 21 at col. 3, lines 25-38. Landers et al. discusses genomic classification based on SNP analysis and the genotyping is done using microarrays.

Landers et al. teaches claim 16 at col. 30, lines 51-67.

Landers et al. teaches claim 18 at col. 5, lines 19-25. Landers et al., discusses using discrete markers for the different alleles.

Claims 1, 5-9, 10-11, 16, and 18 are rejected as being dependent from a rejected claim.

### ***Conclusion***

No claim is allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Sims, whose telephone number is (571)-272-7540.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Andrew Wang can be reached via telephone (571)-272-0811.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571)-273-8300.

Any inquire of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Yolanda Chadwick, whose telephone number is (571)-272-0514.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.



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Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to be 'Carolyn' followed by a stylized flourish.

401631 examiner

9/5/06